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Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number 09/628,387  
Filing Date 08/01/2000  
First Named Inventor Soon-Shiong  
Group Art Unit 1615  
Examiner Name A. Pulliam  
Attorney Docket Number ABI1150-18 (0712400218)

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### U.S. PATENT DOCUMENTS

| Examiner<br>Initials | Doc.<br>No. | U.S. Patent Document            |              | Name of Patentee or Applicant | Date of<br>Publication | Filing Date If<br>Appropriate |
|----------------------|-------------|---------------------------------|--------------|-------------------------------|------------------------|-------------------------------|
|                      |             | Application or<br>Patent Number | Kind<br>Code |                               |                        |                               |
| AUP                  | 1           | 6,096,331                       |              | Desai et al.                  | 08/01/00               |                               |
|                      | 2           | 5,916,596                       |              | Desai et al.                  | 06/29/99               |                               |
|                      | 3           | 5,665,382                       |              | Grinstaff et al.              | 09/09/97               |                               |
|                      | 4           | 5,498,421                       |              | Grinstaff et al.              | 03/12/96               |                               |
|                      | 5           | 5,439,686                       |              | Desai et al.                  | 08/08/95               |                               |
|                      | 6           | 5,362,478                       |              | Desai et al.                  | 11/08/94               |                               |
|                      | 7           | 5,560,933                       |              | Soon-Shiong et al.            | 10/01/96               |                               |
|                      | 8           | 5,641,803                       |              | Carretta et al.               | 06/24/97               |                               |
|                      | 9           | 5,001,235                       |              | Kim                           | 03/19/91               |                               |
|                      | 10          | 5,006,650                       |              | Barbachyn                     | 04/09/91               |                               |
|                      | 11          | 5,015,737                       |              | Kim                           | 05/14/91               |                               |
|                      | 12          | 5,416,071                       |              | Igari et al.                  | 05/16/95               |                               |
|                      | 13          | 5,432,166                       |              | Peck et al.                   | 07/11/95               |                               |
|                      | 14          | 5,434,143                       |              | Spielvogel et al.             | 07/18/95               |                               |
|                      | 15          | 5,442,062                       |              | Koh et al.                    | 08/15/95               |                               |
|                      | 16          | 5,457,119                       |              | Bonjouklian et al.            | 10/10/95               |                               |
|                      | 17          | 5,464,841                       |              | Portoghese et al.             | 11/07/95               |                               |
|                      | 18          | 5,464,865                       |              | Demers et al.                 | 11/07/95               |                               |
|                      | 19          | 5,468,480                       |              | Barrett et al.                | 11/21/95               |                               |
|                      | 20          | 5,468,741                       |              | Yen                           | 11/21/95               |                               |
|                      | 21          | 5,616,320                       |              | Argoudelis et al.             | 04/01/97               |                               |
|                      | 22          | 6,020,368                       |              | Hinks et al.                  | 02/02/00               |                               |
|                      | 23          | 6,218,377                       | B1           | Stogniew et al.               | 04/17/01               |                               |
|                      | 24          | 6,218,426                       | B1           | Anderson et al.               | 04/17/01               |                               |
|                      | 25          | 6,225,311                       | B1           | Levin et al.                  | 05/01/01               |                               |
|                      | 26          | 6,225,342                       | B1           | Habtemariam et al.            | 05/01/01               |                               |
|                      | 27          | 6,228,985                       | B1           | Blood et al.                  | 05/08/01               |                               |
|                      | 28          | 6,239,175                       | B1           | Hinks et al.                  | 05/29/01               |                               |

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Examiner Signature

*[Signature]*

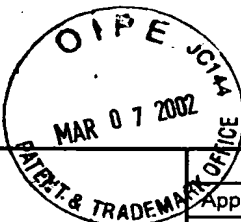
Date Considered

5/14/02

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |                           |    | <b>Complete if Known</b> |             |  |
|  |                           |    | Application Number       | 09/628,387  |  |
|  |                           |    | Filing Date              | 08/01/2000  |  |
|  |                           |    | First Named Inventor     | Soon-Shiong |  |
|  |                           |    | Group Art Unit           | 1615        |  |
| Examiner Name  | A. Pulliam                |    |                          |             |  |
| Attorney Docket Number   | ABI1150-18 (071243-00018) |    |                          |             |  |
| Sheet  | 1                         | of | 3                        |             |  |

**OTHER - NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Doc.<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.   | Translation |      |
|----------------------|-------------|--|-------------|------|
|                      |             |  | Yes         | No++ |
| ALP                  | 1           | O'Connell et al., <i>Phase I Trial of Taxol Given As a Three Hour Infusion Every Three Weeks</i> , 26 Proceedings of the AACR, 169 (Abstract 671) (1985)   |             |      |
|                      | 2           | Longnecker et al., <i>Phase I and Pharmacokinetic Study of Taxol in Patients with Advanced Cancer</i> , 4 Proceedings of ASCO, 32 (C-119) (1985)   |             |      |
|                      | 3           | Donehower et al., <i>Phase I Trial of Taxol in Patients with Advanced Cancer</i> , 71 Cancer Treatment Reports, Vol. 71, No. 12, 1171-77 (Dec. 1987)   |             |      |
|                      | 4           | Waugh et al., <i>Stability, compatability and plasticizer extraction of taxol (NSC-125973) injection diluted in infusion solutions and stored in various containers</i> , Am. J. Hosp. Pharm. Vol. 48, No. 7, 1520-24 (July, 1991)   |             |      |
|                      | 5           | Kris et al., <i>Phase I Of Taxol Given As A 3-Hour Infusion Every 21 Days</i> , 70 Cancer Treatment Reports, 605-607 (1986)  |             |      |
|                      | 6           | Rowinsky et al., <i>Phase II Study of Taxol in Advanced Ovarian Epithelial Malignancies</i> , 7 Proceedings of ASCO (523) (1988)   |             |      |
|                      | 7           | McGuire et al., <i>Taxol: A Unique Antineoplastic Agent With Significant Activity In Advanced Ovarian Epithelial Neoplasms</i> , 111 Annals of Internal Medicine 273-279 (1989)  |             |      |
|                      | 8           | Thigpen et al., <i>Phase II Trial of Taxol as Second-Line Therapy for Ovarian Carcinoma: A Gynecologic Oncology Group Study</i> , 9 Proceedings of ASCO (604) (1990)   |             |      |
|                      | 9           | Rowinsky, <i>Taxol: A Novel Investigational Antimicrotubule Agent</i> , 82 J. Nat. Canc. Inst. 1247-1258 (1990)  |             |      |
|                      | 10          | The American Heritage Dictionary of the English Language 553, 1987 (3d ed. 1992)   |             |      |
|                      | 11          | Remington's Pharmaceutical Sciences 1752-54 (18th ed. 1990)  |             |      |
|                      | 12          | Physicians' Desk Reference 682-85 (49th ed. 1995)  |             |      |
|                      | 13          | Eisenhower et al., <i>European-Canadian Randomized Trial of Paclitaxel in Relapsed Ovarian Cancer: High-Dose Versus Low-Dose and Long Versus Short Infusion</i> , J. Clin. Oncology, 2654-66 (Dec. 1994)   |             |      |
|                      | 14          | The United States Pharmacopeia 24 (Jan. 1, 2000), pp. 1-14 ( <i>General Notices And Requirements</i> ); 1775-1777 (<1> <i>Injections</i> ); 1930-1936 (<661> <i>Containers</i> ); 2107-2228 (<1151> <i>Pharmaceutical Dosage Forms</i> ); 2143-2148 (<1211> <i>Sterilization And Sterility Assurance Of Compendial Articles</i> ). |             |      |
|                      | 15          | Physicians' Desk Reference, 55th.ed. (2001), pp. 1059-1067   |             |      |
|                      | 16          | Dispensing of Medication (John E. Hoover ed., 8th ed. 1976), pp. 1-16 (ch. 1), 255-295 (ch. 10)  |             |      |
|                      | 17          | The Practice of Pharmacy, pp. 404-427, (Donald C. McLeod & William A. Miller eds., 1st ed. 1981)   |             |      |
|                      | 18          | Remington: The Science and Practice of Pharmacy (20th ed.), pp. 780-806 (ch. 41), 807-820 (ch. 42), 1911-1931 (ch. 111)  |             |      |
|                      | 19          | Handbook of Institutional Pharmacy Practice (Mickey C. Smith & Thomas R. Brown eds., 1979) pp. 52-61, 257-289, 302-324, 620-634  |             |      |

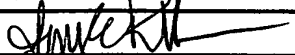
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|----|---|--|--|
| 20 | Practice Standards of ASHP 1996-1997, American Society of Health-System Pharmacists, Practice Standards of ASHP pp. 11, 18-20, 30-38, 96-102, 118-119, 130-146, 165-175, 293-296  |  |  |
| 21 | Fundamentals of Nursing (LuVerne Wolff et al. eds., 6th ed.), pp. 597-644   |  |  |
|    | Packaging Drugs and Pharmaceuticals (Wilmer A. Jenkins & Kenton R. Osborn eds.), pp. 1-9, 32-37, 54-65, 309-326, 332, 343   |  |  |
| 23 | Bryony S. Dean et al., Comparison of medication errors in an American and a British Hospital, <i>Am. J. Health-Syst. Pharm.</i> 52, 2543-9 (1995)   |  |  |
| 24 | Harald O. Schwarz, Bret A. Brodowy, Implementation and Evaluation of an Automated Dispensing System, <i>Am. J. Health-Syst. Pharm.</i> 52, 823-828 (1995)   |  |  |
| 25 | John P. Santell, ASHP National Survey of Hospital-Based Pharmaceutical Services – 1994, <i>Am. J. Health-Syst. Pharm.</i> 52, 1179-1198 (1995)  |  |  |
| 26 | Fred Puckett, Medication-Management Component of a Point-of-Care Information System, <i>Am. J. Health-Syst. Pharm.</i> 52, 1305-1309 (1995)   |  |  |
| 27 | Neil J. Facchinetti et al., Evaluating Error Detection Rates in a Hospital Pharmacy, <i>Med. Care</i> 37, 39-43 (1999)  |  |  |
| 28 | Joseph Perricone, William Hughes, Cost effective method of implementing decentralized unit dose pharmacy services in a Friesen setting, <i>Hospital Pharmacy</i> 19, 817-822 (1984)   |  |  |
| 29 | Katja Taxis et al., Hospital drug distribution systems in the UK and Germany – a study of medication errors, <i>Pharmacy World &amp; Science</i> 21, 25-31 (1999)   |  |  |
| 30 | Compliance Policy Guides Manual, Human Drugs, Chapter 4, § 430.100 United Dose Labeling for Solid and Liquid Oral Dosage Forms (CPG 7132b.10) available at <a href="http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg430-100.html">http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg430-100.html</a>                  |  |  |
| 31 | <i>Dictionary of Pharmacy</i> 74 (University of South Carolina Press) (1986)  |  |  |
| 32 | <i>12 Encyclopedia of Pharmaceutical Technology</i> (James Swarbrick & James C. Boylan eds., 1995)  |  |  |
| 33 | William E. Hassan, Jr., <i>Hospital Pharmacy</i> 278-94 (5th ed. 1986)  |  |  |
| 34 | <i>Human Drugs</i> , Compliance Policy Guides Manual ch. 4, § 480.200, at <a href="http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg480-200.html">http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg480-200.html</a> (August 2001)   |  |  |
| 35 | <i>Guidelines for Unit Dose Dispensing</i> , Arizona Board of Pharmacy Substantive Policies, available at <a href="http://www.pharmacy.state.az.us/link69.htm">http://www.pharmacy.state.az.us/link69.htm</a>   |  |  |
| 36 | Healthcare Compliance Packaging Council, available at <a href="http://www.unitdose.org/">http://www.unitdose.org/</a> ( <i>Glossary of Pharmaceutical Packaging Terms</i> , Healthcare Compliance Packaging Council, available at <a href="http://www.unitdose.org/glossary.htm">http://www.unitdose.org/glossary.htm</a> ) |  |  |
| 37 | Clarence W. Taber, <i>Taber's Cyclopedic Medical Dictionary</i> 1941 (16th ed. 1989)  |  |  |
| 38 | Thomas J. Garrison, <i>Medication Distribution Systems</i> , Handbook of Institutional Pharmacy Practice ch. IV.1, 259 (Mickey C. Smith & Thomas R. Brown eds., 1979)   |  |  |
| 39 | Ken Harms & F. Maurice Smith, <i>Packaging Pharmaceuticals in Institutions</i> , Handbook of Institutional Pharmacy Practice ch. IV.6, 302 (Mickey C. Smith & Thomas R. Brown eds., 1979)   |  |  |
| 40 | Clyde Buchanan, <i>Unit Dose Drug Distribution</i> , The Practice of Pharmacy ch. 33, 404 (Donald C. McLeod & William A. Miller eds.) (1st ed. 1981)  |  |  |
| 41 | <i>ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages</i> , Practice Standards of American Society of Health-System Pharmacists 118-19 (1996-1997)   |  |  |
| 42 | <i>ASHP Statement on Unit Dose Drug Distribution</i> , Practice Standards of American Society of Health-System Pharmacists 11 (1996-1997)   |  |  |
| 43 | Marc R. Summerfield, <i>Unit Dose Primer</i> 9-10 (1983)  |  |  |
| 44 | James C. Boylan et al., <i>Parenteral Products</i> , Modern Pharmaceutics, ch. 12, 441-87 (Gilbert S. Banker & Christopher T. Rhodes eds.) (3rd ed. 1996)   |  |  |

|    |  |  |  |
|----|--|--|--|
| 45 | Best Practices for Health-System Pharmacy, American Society of Health-System Pharmacists (2000-2001 ed.), pp. 42-57, 85, 87-97 |  |  |
| 46 | The Pink Sheet 55(1): 8-9 (January 4, 1993)  |  |  |

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|--------------------|---|-----------------|---------|
| Examiner Signature |  | Date Considered | 5/14/02 |
|--------------------|---|-----------------|---------|

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